

Image

1626

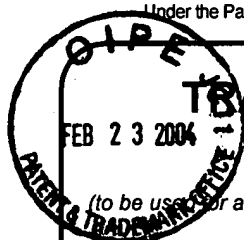
Please type a plus sign (+) inside this box → ☐

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/737,687	
	Filing Date	December 14, 2000
	First Named Inventor	Allen, Darin Arthur
	Group Art Unit	1626
	Examiner Name	WRIGHT, S.
Total Number of Pages in This Submission	Attorney Docket Number	218 US

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Enclosure(s) (please identify below): -Response to Office Action (Re Restriction Requirement 2) – 3 pgs -Petition 1.181 – 5 pgs -Return Postcard
Remarks The Commissioner is authorized to charge any additional fees to Deposit Account 50-0970.		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	CELERA GENOMICS JANICE V. WADE	50,606
Signature	<i>Janice V. Wade</i>	
Date	2-19-2004	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date:		
		February 19, 2004
Typed or printed name	Debra K. Bowen	
Signature	<i>Debra K. Bowen</i>	Date February 19, 2004

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

1626

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Allen, et al.

Application No.: 09/737,687

Filed: 12/14/2000

Title: SALICYLAMIDES AS SERINE PROTEASE
INHIBITORS

Attorney Docket No.: 218 US

Assistant Commissioner for Patents
Washington, D.C. 20231



Group Art Unit: 1626

Examiner: WRIGHT, S.

Reply

Dear Sir:

This is a Petition to the Director to invoke the Director's supervisory authority under 37 C.F.R. § 1.181(a)(3) (2003). A Response to the Office Action dated November 19, 2003 is filed under separate cover.

Remarks

Status of the Claims.

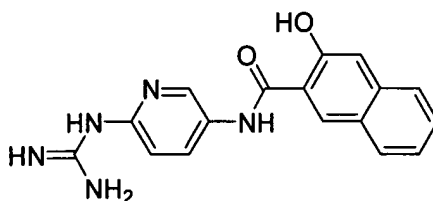
Claims 1-31 are pending in the Application of which Claims 9 and 18-31 are withdrawn from consideration and Claims 1-8 and 10-17 are objected to as containing non-elected subject matter.

Procedural History.

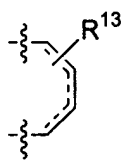
In an Office Action mailed July 30, 2001, the Examiner required the Applicants to elect one of three groups drawn to compounds of Formula I, classified in various classes and subclasses (hereinafter "Restriction Requirement I"). The Examiner further required that the Applicants elect a single disclosed species from within the elected group. In a Response dated October 12, 2001, the Applicants elected Group I the species found on page 66, line 8, of the specification, namely 3-hydroxy-naphthalene-2-carboxylic acid (6-guanidino-pyridin-3-yl)-amide. The Applicants traversed the election of species requirement to the extent that the Examiner intended that the non-elected species would be permanently withdrawn from consideration. Restriction Requirement I was maintained in an Office Action dated December 5,

2001, the Applicants requested reconsideration of the objection to Group I as containing non-elected subject matter in their June 24, 2002 Response. All other substantive issues were resolved and Applicants thus believed the Application was put in condition for allowance. In a final Office Action dated November 20, 2002, the Examiner again maintained the objection to Claims 1-8 and 10-17 as containing non-elected subject matter. The Applicants requested that the Examiner reconsider and also filed a Petition from Requirement for Restriction under 37 C.F.R. § 1.144 (2003). The Petition was granted (hereinafter "Granted Petition") with direction to the Examiner to examine Claim 1 in its full breadth in accordance with M.P.E.P. § 803.02.

On remand, the Examiner made a second Requirement for Restriction mailed on August 4, 2003 (Restriction Requirement II). A Response was made on August 26, 2003 in which the Applicants elected the species found on page 66, line 8, of the Specification, namely 3-hydroxy-naphthalene-2-carboxylic acid (6-guanidino-pyridin-3-yl)-amide,



where, in Formula I, R^1 , R^4 , R^8 , R^9 , R^{20} , and R^{53} are each hydrogen, R^{51} and R^{52} together form =O, R^5 is hydroxy, X, X^2 , X^3 , and X^4 are each carbon, X^1 is nitrogen, and R^2 and R^3 together



form and R^{13} is hydrogen. The Applicants also traversed the Restriction to the extent that nonelected subject matter would be withdrawn from consideration permanently and requested reconsideration.

In an Office Action dated November 19, 2003 the Examiner maintained the Restriction Requirement II and did not extend the search. The Examiner cited 35 U.S.C. 121 and 37 C.F.R. 1.142(b) as authority for restricting the Applicants' Invention. In a Response dated February 19, 2004, Applicants maintained the traversal of the Restriction Requirement II as improper and respectfully requested reconsideration.

Arguments.

Ripeness for Petition

Under the authority of 37 C.F.R. § 1.181 (a) (3) (2003), the Applicants respectfully petition “[t]o invoke the supervisory authority of the Commissioner in appropriate circumstances.” The requirements to petition are as follows:

(c) When a petition is taken from an action or requirement of an examiner in the *ex parte* prosecution of an application, or in the *ex parte* or *inter partes* prosecution of a reexamination proceeding, it may be required that there have been a proper request for reconsideration (§ 1.111) and a repeated action by the examiner.

§ 1.181 (c). The Examiner made a restriction requirement (“Restriction Requirement II”) on August 4, 2003 which stated that “[a]ll compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. [§] 121 and 37 C.F.R. [§] 1.142(b).” In a Response dated August 26, 2003, the Applicants traversed the Restriction Requirement II and requested reconsideration. In a second Office Action dated November 19, 2003, the Examiner repeated the restriction requirement, maintaining it as proper, but did not explicitly make the restriction final. The Applicants believe that this is now a petitionable matter. The Applicants respectfully request that the Director instruct the Examiner to follow the instructions given in the first Petition from Requirement for Restriction dated April 28, 2003 (hereinafter Granted Petition I).

Restriction Requirement.

In the Granted Petition decision, the Director stated “It is clear from the prosecution of the application that the examiner has failed to follow the procedures outlined in M.P.E.P. 803.02 following an election of species.” In the Restriction Requirement II and Office Action mailed subsequent to this decision, the Examiner has not again followed the procedure for treatment of Markush claims as delineated in the M.P.E.P. § 803.02. The Examiner reiterated that the restriction was proper on the grounds that the Markush claim contained patentably distinct inventions, using arguments disallowed by the Office and rejected by the courts as improper. The Applicants emphasize that the standard is patentability and not whether the claim contains patentably distinct subject matter.

The Director, recognizing § 803.02 as the proper procedure, gave direction to the Examiner that “[c]laim 1 will be examined in its full breadth in accordance with M.P.E.P. 803.02” (emphasis added). The Examiner refused to extend the search beyond the elected species and the narrow claim as drawn up by the Examiner. See p. 3 of the Office Action. The nonelected subject matter was then withdrawn from further consideration.

As previously argued by the Applicants, the Examiner’s use of 35 U.S.C. § 121 to restrict and reject the Applicants’ generic Markush claim is in contravention of case law. See *In re Haas*, 486 F.2d 1053 (C.C.P.A. 1973) (*Haas I*) (further proceedings at *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978) (which provides that an objection of the type in this Application amounts to a rejection)); *In re Weber*, 580 F.2d 455, 460 (C.C.P.A. 1978) (“[d]ealing, as it does, with requirements for restriction, § 121 says nothing whatever about the rejection of claims, a matter entirely separate from restriction.”); *Ex parte Holt*, 214 USPQ 381 (Bd. App. 1982) (*Holt I*) (subsequent proceedings at *Ex parte Holt*, 218 U.S.P.Q. 747 (B.P.A.I. 1982); *Rohm and Haas Company v. Robert Gottschalk, Commissioner of Patents*, 504 F.2d 259 (D.C. Cir.1974); and *In re Watkinson*, 900 F.2d 230, 232 (Fed.Cir.1990) (stating that “[u]nder *In re Weber*, ...[at 458] and *In re Haas*, ...[at 464], it is *never* proper for an examiner to reject a Markush claim under 35 U.S.C. § 121.” (Emphasis in the original)). See also Applicants’ previous Responses for detailed arguments.


The Examiner also cites 37 C.F.R. § 1.142(b) for the authority to carve out a subgeneric concept from a claim. However, the Applicants respectfully point out that § 1.142(b) refers to claims being withdrawn, and not subject matter within a claim being withdrawn. Finally, the Examiner asserts that there would be a severe burden to classify, search, and examine the application if not restricted in this manner. However, in the Granted Petition, the Director determined that the examination would not be burdensome, stating that “[s]uch a limited search, even if expanded, could not be considered burdensome to the examiner” (emphasis added). By the Office’s own admission, the examination of the invention as presented by the Applicants would not impose a serious burden on the Examiner.

Summary

In conclusion, the Patent and Trademark Office Board of Patent Appeals and its reviewing court have clearly and unequivocally held that the Patent Office may not require the narrowing of a generic claim pursuant to a restriction requirement. In response to the

Applicants' petition to review Restriction Requirement I, the matter was remanded to the Examiner with instructions to examine claim 1 "in its full breadth in accordance with M.P.E.P. 803.2". Accordingly, the Applicants respectfully request that the remainder of their generically claimed invention be examined on the merits and that, in the absence a statutory or judicially created basis for forming a rejection, Claims 1-8 and 10-17 be allowed. Should the Director deny the Petition under § 1.181, the Applicants will file a Petition from the Requirement for Restriction under 37 C.F.R. § 1.144 (2003).

Respectfully submitted,



Janice V. Wade
Reg. No. 50,606
Agent for the Applicants

February 19, 2004

Celera, An Applera Corporation Business
180 Kimball Way
South San Francisco, CA 94080
Phone: 650.829.1000/Fax 650.866.6651